K002578

4/11/02

1. 510(k) Summary

A. Submitter / 510(k) Sponsor

Karen Jones, Manager of Regulatory Affairs
Edwards Lifesciences
Research Medical
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USA

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B. Date Prepared

2002-03-01

C. Device Name

Axillary Access Arterial Cannula

Classified by FDA under 21 CFR § 870.4210, Cardiopulmonary bypass vascular catheter, cannula, or tubing.

D. Predicate Devices

Predicate Device #1 Name:	Arterial perfusion cannula, ARS022CS
Manufacturer:	Research Medical, Inc. (RMI)
510(k) Number:	K831769
Substantial Equivalence Decision Date:	1983-08-15

Predicate Device #2 Name:	Arterial perfusion cannula, AA020TFA
Manufacturer:	Research Medical, Inc. (RMI)
510(k) Number:	K831769
Substantial Equivalence Decision Date:	1983-08-15

E. Device Description

The RMI Axillary Access Arterial Cannula is a soft PVC cannula, offered in a 22 French size (7.3 mm). With the exception of the tip, it is reinforced with a stainless steel wire coil embedded in the cannula wall to minimize the potential for kinking. The proximal end is terminated with a 3/8" barbed connector.

F. Intended Use

The RMI Axillary Access Arterial Cannula is intended for use in arterial perfusion through the axillary artery for short-term cardiopulmonary bypass (< 6h).

G. Summary of Comparison, Proposed and Predicate Devices

The proposed device is an adaptation of the currently marketed designs for arterial perfusion cannulae, incorporating a 90° bent section at the tip to accommodate the anatomy of the new cannulation site.

The Axillary Cannula has the same ID as the predicate AA020TFA, but has a slightly thicker wall and therefore a slightly larger OD/ French size.

The proposed device also has a modified indication statement. The new indication, for arterial perfusion by cannulation of the axillary artery, does not change the intended use of the predicate devices, which is arterial perfusion during cardiopulmonary bypass. The proposed device, therefore, is substantially equivalent to the predicate devices in intended use.

The proposed device is substantially equivalent to the cited predicate devices in technology, materials and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2002

Ms. Karen Jones
Project Manager, Regulatory Affairs
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

Re: K002578
Trade Name: Axillary Access Arterial Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: January 9, 2002
Received: January 14, 2002

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

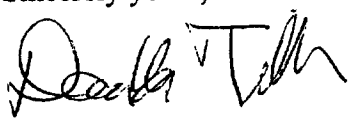
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. Indications for Use Statement

510(k) Number (if known): K002578

Device Name: Axillary Access Arterial Cannula

Indications for use:

The RMI Axillary Access Arterial Cannula is intended for use in arterial perfusion through the axillary artery for short-term cardiopulmonary bypass (< 6h).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002578

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)